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PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

United States Patent and Trademark Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 04 April 1997 (04.04.97)	
International application No. PCT/US96/13615	**Applicant's or agent's file reference** 8648.61WO11
International filing date (day/month/year) 22 August 1996 (22.08.96)	**Priority date** (day/month/year) 22 August 1995 (22.08.95)
Applicant WAGNER, Fred, W. et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

21 March 1997 (21.03.97)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer M. Abidine
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 730.91.11

PATENT COOPERATION TREATY

PCT

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
BRUESS, Steven C.
MERCHANT, GOULD, SMITH, EDELL,
WELTER & SCHMIDT
3100 Norwest Center
90 South Seventh Street
Minneapolis, Minnesota 55402
ETATS-UNIS D'AMERIQUE

NOTIFICATION OF RECEIPT OF DEMAND

(PCT Rule 61.1(b), first sentence and Administrative Instructions, Section 601)

Date of mailing (day/month/year): 01.04.97

Applicant's or agent's file reference: 8648.61WOI1 (P1)

IMPORTANT NOTIFICATION

International application No.	International filing date (day/month/year)	Priority date (day/month/year)
PCT/US 96/13615	22/08/1996	22/08/1995

Applicant: NAUCK, Michael A. ... et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority considers the following date as the date of receipt of the demand for international preliminary examination of the international application:

21/03/1997

2. This date of receipt is:

☒ the actual date of receipt of the demand.

☐ the date on which the proper corrections to the demand were timely received.

3. ☐ This date is AFTER the expiration of 19 months from the priority date.

Attention: The election(s) made in the demand does (do) not have the effect of postponing the commencement of the national phase until 30 months from the priority date (or later in some Offices)(Article 39(1)). Therefore, the acts for entry into the national phase must be performed within 20 months from the priority date (or later in some Offices) (Article 22).

For details, see Annex B to Form PCT/IB/301 sent by the International Bureau and Volume II of the PCT Applicant's Guide.

☐ This notification confirms the information given in person or by telephone on:

4. Only where paragraph 3 applies, a copy of this notification has been sent to the International Bureau.

Name and mailing address of the IPEA/

European Patent Office
D-80298 Munich
Tel. (+49-89) 2399-0, Tx: 523656 epmu d
Fax (+49-89) 2399-6465

Authorized officer

C. Claessens

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (PCT/IPEA/416)
8648.61WOI1		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US96/13615	22/08/1996	22/08/1995
International Patent Classification (IPC) or national classification and IPC		
A61K38/26		
Applicant		
NAUCK, Michael A. ... et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
21/03/1997	20. 11. 97
Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. (+49-89) 2399-0. Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Beeck, M Telephone No. (+49-89) 2399-8473

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US96/13615

I. Basis of th report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1,4-14	as originally filed			
2,3	as received on	25/08/1997	with letter of	21/08/1997

Claims, No.:

1-19	as received on	25/08/1997	with letter of	21/08/1997

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

II. Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

   ☐ copy of the earlier application whose priority has been claimed.

   ☐ translation of the earlier application whose priority has been claimed.

2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid.

Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☐ claims Nos. .

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which do s not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

   ☐ restricted the claims..

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   ☐ all parts.

   ☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-19
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-19
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	10-14,16,19
	No:	Claims	1-9,15,17,18

2. Citations and explanations

siehe Beiblatt, V

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

2. Non-written disclosures (Rule 70.9)

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

V.

1) The documents are numbered according to their sequence in the Search Report.

2) The examiniation has been carried out assuming that the priority is valid. Otherwise P-document D3 should be taken into consideration for the assessment of novelty and inventive step.

3) None of the documents cited in the Search Report describes or suggests nutrient compositions comprising a source of carbohydrate nutrients and one or more insulinotropic peptides.

   Therefore the subject-matter of claims 1 to 19 is novel and involves an inventive step.

4) For the assessment of the present claims 1-9, 15, 17 and 18 on the question whether they are industrially applicable, no unified criteria exist in the PCT. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

administration. When a typical patient receives such parenteral nutrition, the rate of administration is maintained at a low value so that the blood sugar (glucose) level does not exceed the normal physiological range of approximately 60 to 150 mg per dl. These low rates of administration provide an appropriate safety factor to avoid hyperglycemia. Usually, the rates range from 50 to 150 ml per hour of a 5 to 40 wt/wt.% glucose solution.

Nevertheless, nutrition is a fundamental requirement to enable patient healing and sustenance. If patients cannot receive adequate nutrition, as many times occurs with traditional parenteral nutrition, healing takes longer and ancillary problems associated with the patient's primary malcondition often occur. Therefore, there often is a need to deliver parenteral nutrition to a patient at as high a rate as possible while avoiding the deleterious effect of hyperglycemia and avoiding the need for repetitive or continuous insulin administration and titration.

Summary of the Invention

These and other objects are achieved by the invention which is directed to a composition and method for maximal parenteral nutrition substantially without acute or chronic hyperglycemia. The use of the composition in the method of the invention enables delivery of requisite nutrients to satisfy the caloric demand of a patient's healing tissues while at the same time maintaining an appropriate blood glucose level.

The composition of the invention includes a source of nutrients and an insulinotropic peptide. The source of nutrients directly or indirectly provides carbohydrate after administered. Preferably the source of nutrients includes hexoses, pentoses, alcohols thereof and the like, especially those that are highly soluble in aqueous media. Examples include glucose, fructose, galactose, sorbitol, mannitol, xylitol or any combination thereof. Optionally included can be amino acids, electrolytes, lipids, free fatty acids, monoglycerides, diglycerides, triglycerides, glycerol, salts and minerals. The insulinotropic peptide includes gastric inhibitory peptide and its derivatives, glucagon-like peptides such as GLP-1 (1-37) and GLP-1 (7-36), and their derivatives having insulinotropic activity including functional group modifications such as GLP-1 (1-37 amide, GLP-1 (7-36) amide and GLP-1 (7-36)

methyl ester, their peptide sequence fragments such as GLP-1 (7-34), GLP-1 (7-37), GLP-1 (7-36), GLP-1 (7-35), their peptide sequence substitutes such as GLP-1 (7-34) Ala Phe Ala, their peptide sequence deletions such as des (Lys) GLP-1 (7-37) amide, their peptide sequence analogs including those with non-natural amino acid residues, as well as their small organic molecule mimics. The insulinotropic peptide may be a pure single compound, a semi-pure single compound or any mixture of compounds such a mixture of GLP-1 and GIP. The source of nutrients and insulinotropic peptide can be combined in a single aqueous medium or can be contained in separate aqueous media, preferably as a kit. Alternatively, the insulinotropic peptide can be separately formulated in tablet or sustained release matrix form for delivery by a buccal, subcutaneous or other absorption route. The concentrations of nutrients and insulinotropic peptides in the composition are described below.

The method of the invention is accomplished by parenteral administration of the source of nutrients and the insulinotropic peptide. The administration can be accomplished by prior combination of the nutrient source and peptide, by their co-administration from separate sources, by their separate but concomitant administration or by their separate and sequential administration with the insulinotropic peptide being administered first. Individual peptide compounds as well as mixtures of peptide compounds as described above can be administered as the insulinotropic peptide. The route of administration for the nutrients can be any parenteral route such as intraperitoneal or intravenous while the route for the insulinotropic peptide can be the same as or different from the route for the nutrients. The concentration of the insulinotropic peptide used may be any that will deliver and/or maintain normal blood glucose levels in patients who are receiving the source of nutrients according to the invention. The concentrations of nutrients in the nutrient source are at least the same as that typically used for parenteral feeding and the rate of administration is at least the same but is preferably higher than typically prescribed such as preferably a rate providing up to 1000 g of glucose or its equivalent per patient per day. The appropriate dosage of insulinotropic peptide is determined by its sigmoidal dose-response curve relative to the blood glucose level. Consequently, the administration of insulinotropic peptide follows a threshold/increasing level/plateau regimen and is balanced with the rate of administration of the nutrient source so that a

WE CLAIM:

Claim 1. A method for non-alimentary nutrition comprising administering by a parenteral route to a non-diabetic patient in need of parenteral nutrition, a nutrient composition comprising a source of water soluble carbohydrate nutrients and one or more insulinotropic peptides at a standardized concentration.

Claim 2. A method according to claim 1 wherein the source of carbohydrate nutrients directly or indirectly yields glucose when taken up by the body.

Claim 3. A method according to claim 2 wherein the source of carbohydrate nutrients is a hexose, pentose, hexose alcohol, pentose alcohol, or any combination thereof.

Claim 4. A method according to claim 3 wherein the source of carbohydrate nutrients is glucose, fructose, galactose, xylitol, mannitol, sorbitol, or any combination thereof.

Claim 5. A method according to claim 1 wherein the source of carbohydrate nutrients is one or more assimilable amino acids, lipids, free fatty acids, mono- or diglycerides or glycerol.

Claim 6. A method according to claim 2 wherein the administration of the source of carbohydrate nutrients to the patient produces a blood glucose level in the patient of no more than from about 80 to 180 mg glucose per deciliter of blood and the rate of administration of the source of carbohydrate nutrients is calculated to deliver up to about 1000 g of glucose or its equivalent per patient per day.

Claim 7. A method according to claim 1 wherein the administration of the insulinotropic peptide or peptides produces a blood level of the peptide or peptides in the range of 1 pmol per L to 1 mmol per L of blood plasma.

Claim 8. A method according to claim 1 wherein the insulinotropic peptide is GLP-1, GIP, GLP-1 (7-34), GLP-1 (7-35), GLP-1 (7-36), GLP (7-37), the deletion sequences thereof, the natural and non-natural amino acid residue substitutes thereof, the C-

terminus carboxamides thereof, the C-terminus esters thereof, the D-terminus ketones thereof, the N-terminus modifications thereof or any mixture thereof.

Claim 9. A method according to claim 2 wherein the nutrient composition comprises a source of carbohydrate in a first aqueous medium and one or more insulinotropic peptides in a second aqueous medium or a pharmaceutically acceptable solid or gel tab or sustained release matrix.

Claim 10. A nutrient composition comprising a source of carbohydrate nutrients and one or more insulinotropic peptides in an amount calculated to provide a standardized concentration of insulinotropic peptide or peptides when administered to a patient, wherein the nutrients and peptide or peptides are in separate or combined form.

Claim 11. A nutrient composition according to claim 10 wherein the source of carbohydrate nutrient directly or indirectly yields glucose when taken up by the body.

Claim 12. A nutrient composition according to claim 11 wherein the source of carbohydrate nutrient is present at a concentration of about 2% to about 50% by weight of glucose or its equivalent per L.

Claim 13. A nutrient composition according to claim 10 wherein the insulinotropic peptide or peptides are present at a concentration of about 1 nmol per L to about 1 mmol per L.

Claim 14. A nutrient composition comprising a kit containing a first aqueous mixture of a source of carbohydrate nutrients contained in a form for parenteral administration and a second aqueous mixture or solid or gel tab or sustained release matrix of one or more insulinotropic peptides at a standardized concentration and in a form for parenteral administration.

Claim 15. Use of a nutrient composition according to claim 10 for nutrition of a patient.

Claim 16. Use of an insulinotropic peptide in the manufacture of a nutrient composition for parenteral nutrition of a patient comprising preparation of a formulation of a source of carbohydrate nutrients and preparation of a formulation of one or more insulinotropic peptides at a standardized concentration.

Claim 17. A method according to claim 1 wherein the standardized concentration of insulinotropic peptide or peptides being administered is sufficient to provide a plateau level of the insulinotropic peptide or peptides in the patient's blood.

Claim 18. A method according to claim 1 wherein the nutrients and insulinotropic peptide or peptides are continuously and coterminally administered.

Claim 19. A nutrient composition according to claim 10 wherein the standardized concentration of insulinotropic peptide or peptides is sufficient to provide a plateau level of the insulinotropic peptide or peptides in the patient's blood.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
8648.61WOI1		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 96/13615	22/08/1996	22/08/1995
Applicant		
NAUCK, Michael A. ... et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. [X] **Certain claims were found unsearchable** (see Box I).

2. [ ] **Unity of invention is lacking** (see Box II).

3. [ ] The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing
   - [ ] filed with the international application.
   - [ ] furnished by the applicant separately from the international application,
     - [ ] but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
   - [ ] Transcribed by this Authority

4. With regard to the **title,**
   - [X] the text is approved as submitted by the applicant.
   - [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**
   - [X] the text is approved as submitted by the applicant.
   - [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is:

   Figure No. _____
   - [ ] as suggested by the applicant.
   - [ ] because the applicant failed to suggest a figure.
   - [ ] because this figure better characterizes the invention.
   - [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 96/ 13615

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Remark: Although claim(s) 1-5, 8, 9 is(are) directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

2. [X] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

PLEASE SEE NEXT PAGE

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/210

Claims 1-5, 8-14, 16:
A meaningful search is not possible for a composition not more precisely defined than as "comprising a source of nutrients (unspecified) and one or more insulinotropic peptides (also unspecified)".

Most probably not all "insulinotropic peptides" are known at the time of the search. The description (page 2, line 22 - page 3, line 7; page 8, line 23 - page 9, line 9) and claim 8 propose a very wide range of possibilities for these peptides.

From the description (page 2, line 22-29; examples) it appears clearly that one class of nutrients, carbohydrates, especially glucose, is necessary; the other nutrients being optional.

Therefor compositions comprising:
i) carbohydrates, especially glucose, as a source of nutrients;
ii) GLP, GIP or their derivatives as insulinotropic peptides
have been searched.

Claim 4: it has been assumed that "Zylitol" is an error for "Xylitol".

Claims searched incompletely: 1-5, 8-14, 16
Claims not searched: 6, 7, 15

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 96/13615

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61K38/26 A23L1/305

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61K A23L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DIABETES, vol. 34, no. 11, November 1985, pages 1108-1112, XP002023281 A.R.BAER ET AL.: "Effects of Gastric Inhibitory Polypeptide in the Response to Prolonged Pareneteral or Enteral Alimentatation in Rats" see page 1109, column 1, paragraph 2 ---	1-5, 8-13,16
X	SCANDINAVIAN JOURNAL OF GASTROENTEROLOGY, vol. 20, no. 3, - April 1985 pages 321-324, XP002023282 P.F.AMLAND ET AL.: "Effects of Atropine on GIP-Induced Insulin and Pancreatic Polypeptide Release in Man" see page 321, column 2, paragraph 3-4 --- -/--	1-4, 8-14,16

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

2

Date of the actual completion of the international search
22 January 1997

Date of mailing of the international search report
31.01.97

Name and mailing address of the ISA
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Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
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Authorized officer
Van Moer, A

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	DIABETES CARE, vol. 19, no. 8, August 1996, pages 843-848, XP002023283 M.K.GUTNIAK ET AL.: "Potential Therapeutic Levels of Glucagon-like Peptide I Achieved in Humans by a Buccal Tablet" cited in the application see page 844, column 2, paragraph 1 ---	1-4, 8-14,16
X	WO,A,93 18785 (NOVO NORDISK) 30 September 1993 cited in the application see page 8, line 21-23; claims ---	1,2,5, 8-13,16
X	WO,A,93 11799 (PFIZER) 24 June 1993 see claims ---	1,5, 8-13,16
X	EP,A,0 619 322 (PFIZER) 12 October 1994 see claims 1,3,7 ---	1,5, 8-13,16
A	PATENT ABSTRACTS OF JAPAN vol. 017, no. 647 (C-1135), 2 December 1993 & JP,A,05 207846 (SNOW BRAND MILK PROD CO LTD), 20 August 1993, see abstract ---	1
E	DATABASE WPI Section Ch, Week 9651 Derwent Publications Ltd., London, GB; Class B04, AN 96-514913 XP002023284 & JP,A,08 268 908 (GREEN CROSS CORP) , 15 October 1996 see abstract ---	1-5, 8-13,16
P,A	US,A,5 487 898 (MOU-YING F.LU ET AL.) 30 January 1996 cited in the application see claims 1,6,11 -----	

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 96/13615

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A-9318785	30-09-93	AU-A-	3888793	21-10-93
		EP-A-	0631504	04-01-95
		JP-T-	7504669	25-05-95
WO-A-9311799	24-06-93	AU-A-	3058392	19-07-93
		CA-A-	2125400	24-06-93
		EP-A-	0617626	05-10-94
		FI-A-	942938	17-06-94
		HU-A-	69785	28-09-95
		JP-T-	6510796	01-12-94
		NO-A-	942323	17-06-94
		PT-A-	101135	31-03-94
		ZA-A-	9209761	17-06-94
EP-A-619322	12-10-94	AU-A-	5501694	13-10-94
		BR-A-	9401185	18-10-94
		CA-A-	2116478	08-10-94
		CN-A-	1106698	16-08-95
		CZ-A-	9400275	17-05-95
		HU-A-	68525	28-06-95
		JP-A-	7002695	06-01-95
		NO-A-	940436	10-10-94
		NZ-A-	250844	26-03-96
		ZA-A-	9400878	10-08-95
US-A-5487898	30-01-96	US-A-	5284657	08-02-94
		AU-B-	669856	27-06-96
		AU-A-	2519392	16-03-93
		EP-A-	0601053	15-06-94
		JP-T-	6510046	10-11-94
		WO-A-	9303751	04-03-93